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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/982,965	12/02/1997	GEORGE H. LOWELL	359292000110	9909

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EXAMINER
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BUDENS, ROBERT D

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/09/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	08/982,965	LOWELL, GEORGE H.
	Examiner R. Budens	Art Unit 1648
-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --		
<b>Period for Reply</b>		
<p>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</p> <ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>		
<b>Status</b>		
<p>1)<input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>21 October 2002</u>.</p> <p>2a)<input checked="" type="checkbox"/> This action is FINAL.                  2b)<input type="checkbox"/> This action is non-final.</p> <p>3)<input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</p>		
<b>Disposition of Claims</b>		
<p>4)<input checked="" type="checkbox"/> Claim(s) <u>1,3,4 and 7-13</u> is/are pending in the application.</p> <p>4a) Of the above claim(s) _____ is/are withdrawn from consideration.</p> <p>5)<input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6)<input checked="" type="checkbox"/> Claim(s) <u>1,3,4 and 7-13</u> is/are rejected.</p> <p>7)<input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8)<input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.</p>		
<b>Application Papers</b>		
<p>9)<input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10)<input type="checkbox"/> The drawing(s) filed on _____ is/are: a)<input type="checkbox"/> accepted or b)<input type="checkbox"/> objected to by the Examiner.</p> <p style="margin-left: 20px;">Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p>11)<input type="checkbox"/> The proposed drawing correction filed on _____ is: a)<input type="checkbox"/> approved b)<input type="checkbox"/> disapproved by the Examiner.</p> <p style="margin-left: 20px;">If approved, corrected drawings are required in reply to this Office action.</p> <p>12)<input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>		
<b>Priority under 35 U.S.C. §§ 119 and 120</b>		
<p>13)<input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</p> <p>a)<input type="checkbox"/> All    b)<input type="checkbox"/> Some * c)<input type="checkbox"/> None of:</p> <p>1.<input type="checkbox"/> Certified copies of the priority documents have been received.</p> <p>2.<input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.</p> <p>3.<input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</p> <p>* See the attached detailed Office action for a list of the certified copies not received.</p> <p>14)<input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).</p> <p>a)<input type="checkbox"/> The translation of the foreign language provisional application has been received.</p> <p>15)<input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p>		
<b>Attachment(s)</b>		
<p>1)<input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3)<input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.</p> <p>4)<input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>28</u></p> <p>5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6)<input type="checkbox"/> Other:</p>		

**DETAILED ACTION**

The examiner acknowledges Applicant's Amendment, Paper No. 26, filed Oct. 21, 2002. In view of Applicant's Amendment, the status of the claims is as follows: (acknowledging misnumbered claims)

Claims 1, 3-4, 7-10, and newly added claims 11-12 are pending before the Examiner.

Claims 2, 5, and 6 are canceled

***Claim Objections***

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Pursuant to a telephone conversation with Applicant's attorney (see Interview Summary), misnumbered claims 9-12 have been renumbered 10-13, respectively. Future correspondence and communication with the Office must reflect this renumbering. Correction by Applicant is required. As such, the status of the claims is as follows: Claims 1, 3-4, 7-11, and newly added claims 12-13 are pending before the Examiner. Claims 2, 5, and 6 are cancelled.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-4, and 7-13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lowell et al. (U) or Lowell et al. (V) or Smith et al. (W) or Avraham et al. (X) in view of Ratner et al. (Y) for the reasons of record set forth in the last Office Action.

The claimed invention is directed to compositions capable of eliciting antibodies. Applicant's claims are not directed to a vaccine or to a protective immune response to HIV. In Applicant's sole independent claim, claim 1, Applicant has claimed an immunogenic composition comprising proteosomes, gp160 protein, and a pharmaceutical carrier. As such, the only requirement of the claimed invention is that the composition causes the production of antibodies to gp160.

Each of the primary references also teaches the use of similar immunogenic proteosome-protein compositions. Both Lowell et al. (U) and Smith et al. (W) teach the use of proteosomes to enhance the immunogenicity of circumsporozoite peptides. Lowell et al. (V) teach the use of proteosomes to enhance the immunogenicity of membrane glycoprotein peptides. Avraham et al. (X) teach the use of proteosomes to enhance the immunogenicity of HIV-AIDS membrane

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glycoprotein peptides. Avraham et al. also teach the use of a carrier. The primary references do not teach an immunogenic proteosome-gp160 composition.

However, Ratner et al. (Y) teach the gene sequence for a "glycosylated exterior membrane protein" (page 282, column 1). This glycosylated exterior membrane protein is gp160. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute the various immunogenic peptides disclosed in the primary references for the gp160 peptide of Ratner et al. because gp160 was known to be an envelope protein, and it is well known in the viral art that envelope proteins are highly immunogenic compounds. Avraham et al. provide motivation by teaching the use of immunogenic proteosome compositions in the context of HIV-AIDS. Furthermore, Ratner et al. provide motivation by teaching that the complete nucleotide sequence of the HTLV-III provirus will provide useful information for the development of diagnostic and therapeutic reagents to AIDS (page 280, column 1).

Applicant argues that Smith et al. and Aversham et al. are silent as to the details of the technique employed in Applicant's invention. However, Applicant's sole independent claim (claim 1), does not claim a technique. Rather, claim 1 is directed towards a composition.

Applicant points to the unpredictable nature of antibody titers between peptides of different size. Applicant also point to variation in the degree of immunogenicity achieved by the different techniques. However, Applicant is reminded that there is a certain level of unpredictability and variation in any scientific experimentation—but that the degree of unpredictability and variation, in order to be considered nonobvious, must exceed the expectations of the person of ordinary skill in the art. In the present instance, that degree has not been exceeded because, despite any unpredictability and variation, a person of ordinary skill in the art at the time of invention would not have been dissuaded or discouraged from substituting gp160 peptide of Ratner et al. for the other peptides taught by the cited primary references to induce antibody production.

As stated in the previous Office Action, dependent claims 10 and 11 only add further limitations that the complexes are formed by lyophilization or dialysis, both very well known techniques in the art for protein isolation, purification, or storage.

Dependent claim 12 only adds the further limitation that the complexes are formed by mixing. However, the limitation of "mixing" is a very well known technique in the art for combining two or more components and does not render the claim nonobvious.

Dependent claims 3, 4, and 13 only add the further limitation of an adjuvant. However, a person of ordinary skill in the art would have found it obvious to add *any* adjuvant to increase immunogenicity because, by definition, adjuvants increase immunogenicity.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. Budens whose telephone number is 703-308-2960. The examiner can normally be reached on Tuesday - Friday 9-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-5825.

*James C House 9/8/03*  
JAMES HOUSEL for Robert D. Budens  
SUPervisory Patent Examiner Primary Examiner  
TECHNOLOGY CENTER 1600 Art Unit 1648

R. Budens:djv  
September 4, 2003